

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Support for the amendment to claim 45 is found in the specification at page 25, lines 33-35, Figure 3 and page 98, under the heading “(8) Activity evaluation”.

Objections to the Specification

For the following reasons, applicants urge that the specification inherently supports the phrase “caused by the expression of tissue factor” in claim 45. As applicants have demonstrated with the Zhang reference filed with the last response, it was known as of the filing date that tissue factor controls the balance of angiogenic and antiangiogenic activities. As discussed above, the specification discloses that the claimed antibodies inhibit tissue factor and suppress the growth of blood vessel tissues. Accordingly, the specification provides near verbatim support for the phrase “caused by the expression of tissue factor” in claim 45.

Claim Rejections Under 35 USC 112, Written Description

Applicants believe that the amended claims overcome the rejections for lack of written description.

Claim Rejections Under 35 USC 112, First Paragraph

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation” MPEP § 2164, quoting from *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). “The test of enablement is not whether experimentation is necessary, but whether, if experimentation is necessary, it is undue.” MPEP § 2164, quoting from *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed.

Cir. 1985). Applicants contend, that under the guidelines of *In re Wands*, 8583 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), it would not require undue experimentation to carry out the present invention.

With respect to the rejection for lack of enablement, applicants contend that the claims are enabled for the following reasons. Tissue factor is involved with stenosis, restenosis, angiogenesis and neovascularization. Therefore, the inhibition of tissue factor could reasonably be expected to suppress of the growth of blood vessels. Accordingly, because the specification discloses that the claimed antibody is useful for the inhibition of the growth of blood vessels, it is clear that the claimed antibody is useful for treatment of stenosis and restenosis, as well as angiogenesis and neovascularization.

Moreover, Fig. 3 shows that the i-b2 monoclonal antibody binds to a portion of human TF, which binds to Factor X. Therefore, it is clear that human TF is important for inhibition of the growth of blood vessels. In addition, once the i-b2 antibody has been obtained, it would be routine for a person with ordinary skill in the art to obtain antibodies similar to the i-b2 antibody using the same approach.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 27, 2007

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